AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES
	▶		1 | 49

2. CONTRACT (Proc. Inst. Ident.) NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
75A50120C00022	See Block 20C	OS255801

5. ISSUED BY	CODE	ASPR-BARDA	6. ADMINISTERED BY (If other than Item 5)	CODE	ASPR-BARDA
ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201			ASPR-BARDA US DEPT OF HEALTH & HUMAN SERVICES BIOMEDICAL ADVANCED RESEACH & DEVELOPMENT AUT 200 INDEPENDENCE AVE, S.W. Washington DC 20201 SCD-C		

7. NAME AND ADDRESS OF CONTRACTOR (No., street, country, State and ZIP Code)	8. DELIVERY	9. DISCOUNT FOR PROMPT PAYMENT	10. SUBMIT NVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN N	ITEM
GENMARK DIAGNOSTICS, INC. 1487360 GENMARK DIAGNOSTICS, INC. 5964 LA PLACE CT CARLSBAD CA 920088829	☐ FOB ORIGIN ☒ OTHER (See below)		▶	See G.4

CODE	1487360	FAC LITY CODE

11. SHIP TO/MARK FOR	CODE	HHS/OS/ASPR	12. PAYMENT WILL BE MADE BY	CODE	PSC
HHS/OS/ASPR 200 C St SW WASHINGTON DC 20201			PSC Program Support Center 7700 Wisconsin Ave Bethesda MD 20814		

13. AUTHORITY FOR US NG OTHER THAN FULL AND OPEN COMPETITION:	14. ACCOUNTING AND APPROPRIATION DATA
☐ 10 U.S.C. 2304 (c) ( ) ☐ 41 U.S.C. 3304 (a) ( )	2020.199COV3.25106

15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Continued				

15G. TOTAL AMOUNT OF CONTRACT ▶ $749,000.00

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CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. ☒ CONTRACTOR' S NEGOTIATED AGREEMENT (*Contractor is required to sign this document and return* 1 *copies to issuing office.*) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. *(Attachments are listed herein.)*

18. ☐ SEALED-BID AWARD (*Contractor is not required to sign this document.*) Your bid on Solicitation Number _____, including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)

19A. NAME AND TITLE OF SIGNER (Type or print)	20A. NAME OF CONTRACTING OFFICER
Scott O'Brien VP Global Marketing	TROY G. FRANCIS

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
BY DocuSigned by: Scott O'Brien BF42 (Signature of person authorized to sign)	3/20/2020	BY Troy G. Francis -S (Signature of the Contracting Officer)	

Digitally signed by Troy G. Francis -S
DN: c=US, o=U.S. Government, ou=HHS, ou=OS, ou=People, 0.9.2342.19200300.100.1.1=2001931480, cn=Troy G. Francis -S
Date: 2020.03.20 17:59:52 -04'00'

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STANDARD FORM 26 (Rev. 3/2013)
Prescribed by GSA - FAR (48 CFR) 53.214(a)

DS ES DS JB

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED	PAGE	OF
	75A50120C00022	2	49

NAME OF OFFEROR OR CONTRACTOR

GENMARK DIAGNOSTICS, INC. 1487360

ITEM NO. (A)	SUPPL ES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number: 95-4529072 DUNS Number: 962104217 ASPR-20-01405 -- Development of GenMark Dx ePlex Respiratory Pathogen v2 Panel Delivery: 03/20/2020 Appr. Yr.: 2020 CAN: 199COV3 Object Class: 25106 Period of Performance: 03/20/2020 to 07/20/2020				
1	ASPR-20-01405 -- Development of GenMark Dx ePlex Respiratory Pathogen v2 Panel Obligated Amount: $749,000.00				749,000.00

DRIVE EZ-BAA CONTRACT

PART I. THE SCHEDULE

SECTION A. BACKGROUND

In 2018, the Biomedical Advanced Research and Development Authority (BARDA) established the Division of Research, Innovation, and Venture (DRIVe). The mission of DRIVe is to encourage agile business practices, accelerate biomedical innovations, and improve the availability of transformative products & technologies to protect Americans from natural and intentional health security threats. The following contract and the Statement of Work (addressed in Section C), further the mission and goals of DRIVe.

SECTION B. SUPPLIES OR SERVICES AND PRICE/COST

B. 1. PRICE

FIRM FIXED PRICE: The firm fixed price of the base period of the contract is $749,000.

.

CONTRACT LINE ITEM NO. (CLIN)	PROJECT DESCRIPTION	PERIOD OF PERFORMANCE	QUANTITY	UNIT	UNIT PRICE
0001	Development of GenMark Dx ePlex® Respiratory Pathogen v2 Panel	20 March 2020 - 20 July 2020	1	JOB	$749,000

Through negotiations, the Government and Contractor agreed that a total price of $1,404,731 would be a realistic and reasonable estimate of Contractor's actual costs of performance. Accordingly, in return for successful completion and delivery of CLIN 0001, the Government's portion will be $749,000.

B. 2. ADVANCE UNDERSTANDINGS

a. **Sharing of contract deliverables within United States Government (USG)**

In an effort to build a robust medical countermeasure pipeline through increased collaboration, the Government may share technical deliverables with Government entities responsible for Medical Countermeasure Development. In accordance with recommendations from the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) Review, agreements established in the Integrated Portfolio Advisory Committee (PAC) Charter, and agreements between BARDA and the Department of Defense, the National Institutes of Health, the Centers for Disease Control, and the FDA, BARDA may share technical deliverables and test results created in the performance of this Contract with colleagues within the PHEMCE as well as within the Department of Health and Human Services (DHHS). This advance understanding does not authorize the Government to share financial information outside of the United States Government. The Contractor is advised to review the terms of FAR 52.227-14 Rights in Data – General, regarding the Government's rights to data produced during the course of performance of this Contract.

b. **Approval of Human and Animal Protocols**

This contract:

1. ☒ **Will** or ☐ **Will Not** include clinical trials (e.g. human protocols); and
2. ☐ **Will** or ☒ **Will Not** include non-clinical trials (e.g. animal protocols).

Accordingly, if checked to indicate either class of studies is *not* included under the subject contract, all of the corresponding clinical and non-clinical clauses, terms, and obligations included in this document are hereby self-deleted.

The Contractor shall submit all human and animal protocols and human informed consent documents as referenced under this Contract to the Contracting Officer (CO) and Contracting Officer's Representative (COR) for review and approval **prior** to seeking other approvals (Institutional Review Board, Human Use Committee, Institutional Animal Care and Use Committee). The Government requires no fewer than eight (8) business days to perform a review. The Contractor shall take this review time into account and submit protocols as early as possible to avoid delays. The Government's comments and feedback shall be addressed prior to approval. The COR will review and provide approval of protocols. Human informed consents shall also be submitted and reviewed with any human protocol.

c. **Rights in Data**

See Section I – Contract Clauses

SECTION C. DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

C.1. STATEMENT OF WORK

See Section J – Attachment 1 (Statement of Work) as agreed upon by the Government and Contractor, and the Reporting Requirements outlined by "DRIVe Digital Resources" accessed via www.drive.hhs.gov.

C.2 REGULATORY ACTIVITIES

The Contractor shall submit to the COR for review and comment, pre-submission documents, submission documents, results documents, and all proposed regulatory filing documents with the FDA.

C.3 QUALITY

The Contractor may be required to establish and maintain a Quality Management System for the proposed effort with sufficient content to include but not limited to the elements contained in the Code of Federal Regulations Title 21 Part 820.

The Contractor may be required to establish routine internal reviews of the proposed effort with documentation and evidence of the ability to maintain, and adhere to the Code of Federal Regulations Title 21 Part 820.

The Contractor may be required to subcontract for an independent audit of its system quality system adherence, resolve any issues noted by the auditor, and provide the audit findings and resolutions to the Government.

SECTION D. PACKAGING, MARKING, AND SHIPPING

All deliverables required under this Contract shall be packaged, marked and shipped in accordance with Government specifications and Section F. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

Unless otherwise specified by the CO, delivery of reports to be furnished to the Government under this Contract (including invoices) shall be delivered to the CO and COR electronically along with a concurrent email notification to the CO and COR (as defined in Section F.3. Electronic Submission) summarizing the electronic delivery.

SECTION E. INSPECTION AND ACCEPTANCE

E.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

See Section I for a complete list of clauses incorporated by reference.

E.2. DESIGNATION OF GOVERNMENT PERSONNEL

For the purpose of this Section E, the designated COR is the authorized representative of the CO. The COR will assist in resolving technical issues that arise during performance. The COR however is not authorized to change any contract terms or authorize any changes in the Statement of Work, modify or extend the period of performance, or authorize reimbursement of any costs incurred during performance.

E.3. INSPECTION, ACCEPTANCE AND CONTRACT MONITORING

Inspection and acceptance of the product, services, and documentation called for herein shall be accomplished by the CO or a duly authorized representative. Delivery, technical inspection and acceptance will be take place at a location designated by the CO or at:

Office of the Assistant Secretary for Preparedness and Response
Biomedical Advanced Research and Development Authority
O'Neill House Office Building
Washington, DC 20515

At the discretion of the Government and independent of activities conducted by the Contractor, with 48 hours' notice to the Contractor, the Government reserves the right to conduct site visits and inspections related to this Contract on an as needed basis during normal business hours, including collection of product samples and intermediates held at the location of the Contractor, or its subcontractor. All costs reasonably incurred by the Contractor and subcontractor for such visit and/or inspection shall be allowable costs subject to the Allowable cost requirements in FAR Subpart 31.2. The Contractor shall coordinate these visits and shall have the opportunity to accompany the Government on any such visits. Under time-sensitive or critical situations, the Government reserves the right to suspend the 48 hour notice to the Contractor. The areas included under the site visit could include, but are not limited to: security, regulatory and quality systems, manufacturing processes and cGMP/GLP/GCP compliance related to activities funded under this Contract.

If the Government, Contractor, or other party identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government for review and acceptance.

- If issues are identified during the audit, the Contractor shall submit a report to the CO and COR within five (5) business days detailing the finding and corrective action(s) of the audit.
- COR and CO will review the report and provide a response to the Contractor within ten (10) business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

SECTION F. DELIVERIES OR PERFORMANCE

F.1. ESTIMATED PERIOD OF PERFORMANCE

The estimated period of performance for this Contract shall be consistent with the dates set forth in Section B.2.

F.2. DELIVERABLES

Successful performance under this contract shall be deemed to occur upon completion of performance of the work set forth in Attachment 1 of this contract and upon delivery and acceptance, as required by Attachment 1, by the COR, and of each of the deliverables described in Section C and Section F below.

All deliverables and reporting documents listed within this Section shall be delivered electronically to the CO, the Contract Specialist (CS), and the COR as well as in the designated eRoom (the Government's SharePoint site) unless otherwise specified by the CO.

Number	Deliverable	Description	Due
1	Kickoff Meeting	The Contractor shall complete a Kickoff meeting after contract award, either as a videoconference or an in-person meeting, to outline activities for the next 30 days. The Contractor shall provide an itinerary and agenda at least 2 business days in advance of meeting.	Within 10 days of award date.
2	Weekly Teleconference	The Contractor shall participate in teleconferences every week with BARDA to discuss the performance of the contract. The Contractor shall provide slides 24 hours in advance of scheduled meetings.	Held weekly. Minutes provided by Contractor within 3 business days of the meeting.
3	Daily Check-In with Project Staff for COVID-19 Response	Upon request of the Government, the Contractor shall participate in a daily check-in updates with the project staff (via teleconference or email). The updates will address key cost, schedule and technical updates. Daily updates may be shared with senior Government leaders during the COVID-19 response and should be provided in both a non-confidential and confidential format. Daily check-ins may occur on weekdays, excluding federal holidays. Upon request of the Government, check-ins may also occur on weekends and on federal holidays, provided at least 8 hours' notice.	No agenda will be required for the check-in. No meeting minutes are required. Contractor will provide a bulleted email update as soon as possible following any check-in.
4	Monthly Reports	Submit monthly reports summarizing data and progress to date on each aim in the SOW.	Due the 15th of the month following the preceding reporting month. The COR and CO will review the monthly reports with the Contractor and provide feedback.
5	Product Development Source Material and Manufacturing Report	The Contractor shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites; and	Within 30 days of award date, and within 30 days after substantive changes are made to sources or materials. The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after

		location and nature of non-clinical and clinical study sites.	submission. If corrective action is recommended, Contractor must address and document all concerns raised by BARDA.
6	Work Location Tracking	The Contractor shall submit a detailed spreadsheet regarding locations where work will be performed under this contract, including addresses, points of contact, and work performed per location, to include any subcontractors, if necessary.	Within 5 business days of award date, and within 30 days after substantive changes are made to locations or capabilities. Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO
7	Product/Technology Transition Strategy	Contractor shall provide a 1-2 page summary document containing a Transition Strategy. The Transition Strategy should provide a strategic business and technical plan for further development and transitioning the product and/or technology	Contractor shall provide the Transition Strategy 30 days prior to the end of each year of the Base Period.
8	Sample Prototype	If applicable and available, the Contractor shall deliver sample prototype/examples to BARDA DRIVe for display purposes ONLY. Prototype/examples are not intended for clinical or non-clinical uses.	Prototype shall be delivered 30 days from request if available
9	Final Data Submission Package	Contractor must submit a data package consisting of all raw data produced under this contract. Data may be used by BARDA DRIVe for analysis, evaluation, shared with other agencies, or shared outside of the government consistent with FAR 52.227-14. This submission package must be delivered in a non-proprietary format. If clinical trial data is included, that data must be provided consistent with applicable privacy laws to protect personally identifiable information (PII).	Contractor will submit at least 15 days prior to contract end date. Partial data-sets may also be requested for delivery prior to submission of the Final Data Submission Package.

10	Draft Final Report & Final Report	These reports are to include a summation of the work performed and results obtained for the entire contract period of performance.	Draft Final Report to the COR and CO 30 calendar days prior to contract end date; Final Report shall be delivered on or before the completion date of the contract.
11	Supplemental Technical Documents, Raw Data, or Data Analysis	The Contractor shall provide all raw data, data analysis, or a data report to BARDA DRIVe in accordance with FAR 52.227-14.	Contractor shall provide the Technical Documents, Raw Data, or Data Analysis upon request from the CO or COR
12	Deliverables Arising from FDA Correspondence	See descriptions below for FDA Meetings, FDA Submissions & Correspondence, FDA Audits, and Other FDA Correspondence.	See descriptions below for FDA Meetings, FDA Submissions & Correspondence, FDA Audits, and Other FDA Correspondence.

a. **Periodic Document Review**

The CO and COR reserve the right to request within the period of performance a non-proprietary technical document for distribution within the Government. Contractor shall provide the technical document within 10 business days of CO or COR request. Contractor can request additional time on an as-needed basis. If edits are recommended, the Contractor must address, in writing, concerns raised by the Government in writing.

b. **Deliverables Arising from FDA Correspondence**

1) FDA Meetings

i. The Contractor shall forward the dates and times of any meeting with the FDA to BARDA and make arrangements for appropriate BARDA staff to attend the FDA meetings if requested by BARDA. BARDA may include up to a maximum of four people (COR, CO and up to 2 subject matter experts).

ii. Contractor shall notify BARDA of upcoming FDA meetings within 24 hours of scheduling.

iii. The Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA to the CO and COR within 5 business days of receipt. All documents shall be duly marked as either “Draft” or “Final.”

2) FDA Submissions & Correspondence

i. The Contractor shall provide BARDA the opportunity to review and comment upon all documents submitted to the FDA. In addition, an electronic copy of the final FDA submissions will also need to be submitted. All documents shall be duly marked as either “Draft” or “Final.”

1. If draft documents are submitted to the COR for review, the COR will provide feedback to Contractor within 10 business days of receipt, or sooner as necessary to address FDA deadlines or requests.

2. If BARDA reviews draft documents, the Contractor shall revise, as appropriate, their documents to address BARDA's concerns and/or recommendations prior to FDA submission.

3. Final FDA submissions and all email correspondence with the FDA related to submissions shall be submitted to the CO and COR no later than 5 calendar days of their submission to, or email correspondence with, the FDA.

3) FDA Audits

i. In the event of an FDA inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the CO and COR with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR) within five (5) business days after the Contractors receipt of those documents. The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. To the extent feasible, the Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector.

ii. If draft documents are submitted to the COR for review, the COR will provide feedback to Contractor within 10 business days of receipt, or sooner as necessary to address FDA deadlines or requests.

iii. If BARDA reviews draft documents, the Contractor shall revise as appropriate their documents to address BARDA's written concerns and/or recommendations prior to FDA submission.

1. Contractor shall notify CO and COR within 10 business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide 10 business days' advance notice.

2. Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within 5 business days of receiving correspondence from the FDA, Subcontractor, or third party.

3. Within 15 business days of audit report, Contractor shall provide CO with a plan for addressing areas of nonconformance, if any are identified.

Final FDA submissions shall be submitted to the CO and COR.

4) Other FDA Correspondence

The Contractor shall document any material correspondence between Contractor and FDA as related to activities funded under this contract and submit to BARDA. All such documents shall be duly marked as either "Draft" or "Final." Contractor shall provide such written summary of any FDA correspondence or engagement within 5 business days and submit to the CO and COR. The written summary shall include:

i. A tracking log of progress on regulatory submissions with the FDA, description of the submission, date of the submission, status of submission and next steps.

c. **Reporting and Meeting Details Specifics**

Monthly Progress Report:

This report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

The Contractor shall submit a Monthly Progress Report on or before the 15th calendar day following the last day of each reporting period and shall include the following:

A cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission;

SECTION I - An introduction covering the purpose and scope of the contract effort;

SECTION II – PROGRESS

SECTION II Part A: OVERALL PROGRESS - A description of overall progress;

SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE – A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. evaluating and managing subcontractor performance and personnel changes);

SECTION II Part C: TECHNICAL PROGRESS - For each activity related to the Gantt chart, document the results of work completed. The report shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the Contract. Include progress or status updates for all SOW tasks in each of the monthly technical progress reports for which there is activity ongoing in that SOW task area(s) as well as data for completed studies in any SOW task.

The report shall also include a description of problems encountered and proposed corrective action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned; preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project;

SECTION II Part D: PROPOSED WORK - A summary of work proposed for the next reporting period and preprints/reprints of papers and abstracts, and a current/updated Gantt chart;

SECTION II Part E: Outstanding Issues/Anticipated Areas of Concern - a list of any existing contractual concerns that impact the technical scope of work, schedule, or pricing, as well as a list of potential or anticipated areas of concern that may be encountered in the future months. A Monthly Progress Report will not be required in the same month that the Annual or Final Reports are submitted;

Final Report(s) Requirement:

This report shall include a summation of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full year of performance plus any fractional part of the initial year. Thereafter, the reporting period shall consist of each calendar year.

The report shall include a cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission;

SECTION I-EXECUTIVE SUMMARY - A brief overview of the work completed and major accomplishments achieved during the reporting period;

SECTION II-PROGRESS

SECTION II Part A: OVERALL PROGRESS - A description of overall progress highlighting the significant accomplishments in the past year;

SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE – A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. evaluating and managing subcontractor performance and personnel changes;

SECTION II Part C: TECHNICAL PROGRESS - For each activity, document the results of work completed during the period covered in relation to proposed progress, effort and budget. The report shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the Contract. The report shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned; preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project. The report should summarize progress made under each SOW task.

Monthly Calls

A conference call between the COR and the Contractor's Project Leaders/delegates and designees shall occur monthly or as directed by the CO and COR. During this call the Contractor's Project Leaders/delegates and designees will discuss the activities since the last call, any problems that have arisen and the activities planned until the next call takes place. The Contractor's Project Leaders/delegates may choose to include other key personnel on the conference call to give detailed updates on specific projects as this may be requested by the COR.

Project Meetings

The Contractor shall participate in Project Meetings to coordinate the performance of the Contract, as requested by the COR. These meetings may include face-to-face meetings (kick-off meetings, project reviews, etc) with BARDA in Washington, D.C. and at work sites of the Contractor. Such meetings may include, but are not limited to, meetings of the Contractor to discuss study designs, site visits to the Contractor's facilities, and meetings with the Contractor and DHHS officials to discuss the technical, regulatory, and ethical aspects of the program. Subject to the data rights provisions in this Contract, the Contractor will provide data, reports, and presentations to groups of outside experts and Government personnel as required by the CO and COR in order to facilitate review of contract activities.

Electronic copies of the conference call meeting minutes/summaries by the Contractor shall be provided via e-mail to the CO and COR by the Contractor within five (5) business days after the conference call is held. The COR will review these minutes for approval within 15 business days.

d. **Experimental Protocols**

Notwithstanding guidance found under Article H in this document related to clinical protocols, the Contractor shall submit all study/experiment/test plans, designs, and other protocols to BARDA for review and comment before proceeding with a study.

F.3 SUBJECT INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11 Patent Rights-Ownership by the Contractor, including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the CO. A final invention statement (see FAR 27.303 (b)(2)(ii)) shall be submitted to the CO prior to the closeout of the Contract.

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the CO at the address listed below.

SECTION G – CONTRACT ADMINISTRATION DATA

G.1. CONTRACTING OFFICER

The following CO will represent the Government for the purpose of this Contract:

Troy Francis
Contracting Officer
HHS/ASPR/AMCG
O'Neill House Office Building
Washington, DC 20515
troy.francis@hhs.gov

1) The CO is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the CO can make any changes to the terms, conditions, general provisions, or other stipulations of this Contract.
2) The CO is the only person with the authority to act as agent of the Government under this contract. Only the CO has authority to (1) direct or negotiate any changes in the Statement of Work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor of any costs incurred during the performance of this Contract; (5) otherwise change any terms and conditions of this Contract.
3) No information other than that which may be contained in an authorized modification to this Contract, duly issued by the CO, which may be received from any person employed by the Government, other otherwise, shall be considered grounds for deviation from any stipulation of this Contract.
4) The Government may unilaterally change its CO designation, after which it will notify the Contractor in writing of such change.

G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following COR will represent the Government for the purpose of this contract:

John Esker
Contracting Officer's Representative
HHS/ASPR/BARDA
O'Neill House Office Building
Washington, DC 20515
john.esker@hhs.gov

The COR is responsible for:

1) Monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the CO changes in requirements;
2) Assisting the CO in interpreting the Statement of Work and any other technical performance requirements;
3) Performing technical evaluation as required;
4) Performing technical inspections and acceptances required by this Contract; and

5) Assisting in the resolution of technical problems encountered during performance. The Government may unilaterally change its COR designation, after which it will notify Contractor in writing of such change.

G.3. KEY PERSONNEL

Pursuant to the Key Personnel clause incorporated in Section I of this Contract, the following individuals are considered to be essential to the work being performed hereunder:

Name	Title
Alan Maderazo	VP, Quality, Regulatory & Clinical Affairs
Ganesh Paranthaman	Director, Program Management
Christine Shaw	Senior Director, Assay Development

The key personnel specified in this Contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the CO and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) and qualifications (CV, etc) of the individual proposed as a substitute to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the CO. The Government may modify the contract to add or delete key personnel at the request of the contractor or Government.

G.4. INVOICING

a. Invoices (see Attachment 2) will be submitted for each deliverable in accordance with Attachment 3. In the event that a deliverable is not submitted or not deemed acceptable for approval by the COR and CO, the CO reserves the right to not process the invoice and payment until an acceptable deliverable has been submitted and approved by the COR and CO.

b. Unless otherwise stated in the instructions for completing this form, all columns A through H, shall be completed for each report submitted.

c. The first financial report shall cover the period consisting of the first full three calendar months following the date of the Contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a quarterly basis.

d. The CO may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.

e. The listing of expenditure categories to be reported is incorporated as a part of this Contract and can be found at Attachment 2.

f. Invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.

g. Contractor invoices/financial reports shall conform to the form, format, and content requirements of the instructions for Attachment 2, and be sent electronically to the following points of contact*. Additionally, the Contractor may be required to submit to a DRIVe specific invoice tracking system as will be directed by the CO.

h. An electronic copy of the payment request shall be uploaded into the designated digital repository (DRIVe Digital Resources) and an e-mail notification of the upload will be provided to the CO and COR.

CO	COR	PSC
Troy Francis Contracting Officer troy.francis@hhs.gov	John Esker Contracting Officer's Representative john.esker@hhs.gov	PSC_Invoices@psc.hhs.gov

* All invoice submissions shall be in accordance with FAR Clause 52.232-25, Prompt Payment (Oct 2008)

G.5. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this Contract in accordance with FAR Subpart 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, an interim evaluation shall be submitted annually.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the CO. Should Contractor choose to do so, it may challenge that individual's decision in accordance with FAR 52.233-1, incorporated herein by Section I.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

http://www.cpars.csd.disa.mil/cparsmain.htm

The registration process requires the Contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the Contractor will be required to identify an alternate contact that will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

G.6. CONTRACT COMMUNICATIONS/CORRESPONDENCE (JULY 1999)

The Contractor shall identify all correspondence, reports, and other data pertinent to this Contract by imprinting the contract number from Page 1 of the Contract.

G.7. GOVERNMENT PROPERTY

Contractor retains title to all property acquired as necessary to execute the work under this contract.

SECTION H – SPECIAL CONTRACT REQUIREMENTS

H.1 REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in BARDA funded programs should report such matters to the DHHS Inspector General's Office in writing or on the Inspector

General's Hotline. The toll free number is 1-800-HHS-TIPS (1-800- 447-8477). All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services TIPS
HOTLINE
P.O. Box 23489 Washington, D.C. 20026

H.2 PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this Contract.

H.3 IDENTIFICATION AND DISPOSITION OF DATA

The Contractor will be required to provide certain data generated under this Contract to DHHS. DHHS reserves the right to review any other data related to performance of this Contract.

The Contractor shall keep copies of all data required by the FDA relevant to this Contract for the time specified by the FDA.

H.4 EXPORT CONTROL NOTIFICATION

Contractors are responsible for ensuring compliance with all export control laws and regulations that may be applicable to the export of and foreign access to their proposed technologies. Contractors may consult with the Department of State with any questions regarding the International Traffic in Arms Regulation (ITAR) (22 C.F.R. Parts 120-130) and /or the Department of Commerce regarding the Export Administration Regulations (15 C.F.R. Parts 730-774).

H.5 CONFLICT OF INTEREST

The Contractor represents and warrants that, to the best of the Contractor's knowledge and belief, there are no relevant facts or circumstances which could give rise to an organizational conflict of interest, as defined in FAR 2.101 and Subpart 9.5, or that the Contractor has disclosed all such relevant information. Prior to commencement of any work, the Contractor agrees to notify the CO promptly that, to the best of its knowledge and belief, no actual or potential conflict of interest exists or to identify to the CO any actual or potential conflict of interest the firm may have. In emergency situations, however, work may begin but notification shall be made within five (5) working days. The Contractor agrees that if an actual or potential organizational conflict of interest is identified during performance, the Contractor shall promptly make a full disclosure in writing to the CO. This disclosure shall include a description of actions which the Contractor has taken or proposes to take, after consultation with the CO, to avoid, mitigate, or neutralize the actual or potential conflict of interest. The Contractor shall continue performance until notified by the CO of any contrary action to be taken. Remedies include termination of this Contract for convenience, in whole or in part, if the CO deems such termination necessary to avoid an organizational conflict of interest. If the Contractor was aware of a potential organizational conflict of interest prior to award or discovered an actual or potential conflict after award and did not disclose it or misrepresented relevant information to the CO, the Government may terminate the Contract for default, debar the Contractor from Government contracting, or pursue such other remedies as may be permitted by law or this Contract.

H.6 INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

The Contractor shall comply with the requirements of 45 C.F.R. Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that investigators (defined as

the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded under BARDA contracts) will not be biased by any conflicting financial interest.

As required by 45 C.F.R. Part 94, the Contractor shall, at a minimum:

a. Maintain a written, enforceable policy on conflict of interest that complies with 45 C.F.R. Part 94 and inform each investigator of the policy, the investigator's reporting responsibilities, and the applicable regulations. The Contractor must take reasonable steps to ensure that investigators working as collaborators or subcontractors comply with the regulations.

b. Designate an official(s) to solicit and review financial disclosure statements from each investigator participating in BARDA-funded research. Based on established guidelines consistent with the regulations, the designated official(s) must determine whether a conflict of interest exists, and if so, determine what actions should be taken to manage, reduce, or eliminate such conflict. A conflict of interest exists when the designated official(s) reasonably determines that a *Significant Financial Interest* could directly and significantly affect the design, conduct, or reporting of the BARDA-funded research. The Contractor may require the management of other conflicting financial interests in addition to those described in this paragraph, as it deems appropriate. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests are included in 45 C.F.R. Part 94, under Management of Conflicting Interests.

c. Require all financial disclosures to be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

d. Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the Contractor with respect to each conflicting interest 3 years after final payment or, where applicable, for the other time periods specified in 48 C.F.R. Part 4, subpart 4.7, Contract Records Retention.

e. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.
If a conflict of interest is identified, the Contractor shall report to the CO, the existence of the conflicting interest found. This report shall be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis, within sixty (60) days of that identification.

If the failure of an investigator to comply with the conflict of interest policy has biased the design, conduct, or reporting of the BARDA-funded research, the Contractor must promptly notify the CO of the corrective action taken or to be taken. The CO will take appropriate action or refer the matter to the Contractor for further action, which may include directions to the Contractor on how to maintain appropriate objectivity in the funded research.

The CO may at any time inquire into the Contractor's procedures and actions regarding conflicts of interests in BARDA-funded research, including a review of all records pertinent to compliance with 45 C.F.R. Part 94. The CO may require submission of the records or review them on site. On the basis of this review, the CO may decide that a particular conflict of interest will bias the objectivity of the BARDA-funded research to such an extent that further corrective action is needed or that the Contractor has not managed, reduced, or eliminated the conflict of interest. The issuance of a Stop Work Order by the CO may be necessary until the matter is resolved.

If the CO determines that BARDA-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an investigator with a conflict of interest that was not disclosed or managed, the Contractor must require disclosure of the conflict of interest in each public presentation of the results of the research.

H.7 NEEDLE DISTRIBUTION

The Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

H.8 DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

H.9 CONFIDENTIALITY OF INFORMATION

a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The CO and the Contractor may, by mutual consent, identify elsewhere in this Contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential and providing further that the Government is not entitled to unlimited rights to that information pursuant to FAR 52.227-14. Similarly, the CO and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this Contract that information to be utilized under this Contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the Contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the CO prior to any release, disclosure, dissemination, or publication.

f. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

H.10 ACCESS TO DOCUMENTATION/DATA

The Government shall have physical and electronic access to all documentation and data generated under this Contract, including: all data documenting Contractor performance; all data generated; all communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, milestone completion documents, and all Offeror commitments and responses. Contractor shall provide the Government with an electronic copy of all correspondence and submissions to the FDA within 5 business days of receipt. The Government shall acquire unlimited rights to all data funded under this contract in accordance with FAR Subpart 27.4 and FAR Clause 52.227-14.

H.11 [Reserved]

H.12 ACKNOWLEDGMENT OF FEDERAL FUNDING

Section 507 of P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. This requirement is in addition to the continuing requirement to provide an acknowledgment of support and disclaimer on any publication reporting the results of a contract funded activity.

Publication and Publicity

No information related to data obtained under this Contract shall be released or publicized without providing BARDA with at least thirty (30) days advanced notice and an opportunity to review the proposed release or publication.

In addition to the requirements set forth in this Contract, Section 507 of P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. Contractors are required to state:

(1) The percentage and dollar amounts of the total program or project costs financed with Federal money and;

(2) The percentage and dollar amount of the total costs financed by non-governmental sources. For purposes of this Contract "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information, including any manuscript or scientific meeting abstract. Any publication containing data generated under this Contract must be submitted for BARDA review no less than thirty (30) calendar days for manuscripts and fifteen (15) calendar days for abstracts before submission for public presentation or publication. Contract support shall be acknowledged in all such publications substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. 75A50120C00022."

Press Releases

Misrepresenting contract results or releasing information that is injurious to the integrity of BARDA may be construed as improper conduct. Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. With the exception of ad-hoc press releases required by applicable law or regulations, the Contractor shall ensure that the COR has received an advance copy of any press release related to the contract not less than two (2) business days prior to the issuance of the press release.

The Contractor shall acknowledge the support of the Department of Health and Human Service, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, Division of Research Innovation and Ventures under Contract No. 75A50120C00022."

a. Contractor Use of the Powered by DRIVe Logo

1) For the limited purposes of the Contractor's participation related to the subject DRIVe contract, Contractor is permitted to use the following logo (the "Logo") for the period of performance of this Contract (or for a longer period, if agreed between the parties), subject to the Contractor's full performance of the terms and conditions of the subject Contract and provided that Contractor shall cease to use the Logo immediately upon BARDA's request.

2) The Contractor's use of the term "Powered by DRIVe" shall be subject to DRIVe Brand Guidelines.

3) Any other use of the DRIVe name, its Logo, service marks or trademarks, or any of its other distinguishable marks, whether registered or not, shall be limited to those granted by the express, written permission of the BARDA. Those to whom such permission is granted must agree that BARDA shall remain the final arbiter of the use of the mark or Logo.

b. BARDA Use of Contractor Logo

Contractor hereby grants BARDA/DRIVe the right to use Contractor's corporate logo (and other artwork as agreed to by the parties), for presentations, internal and external websites, and other reasonable promotional and reporting uses relating to the project during the period of performance of the Contract (or for a longer period, if agreed between the parties).

H.13 [Reserved]

H.14 PRIVACY ACT APPLICABILITY

Notification is hereby given that the Contractor and its employees are subject to criminal penalties for violation of the Privacy Act to the same extent as employees of the Government. The Contractor shall assure that each of its employees knows the prescribed rules of conduct and that each is aware that he or she can be subjected to criminal penalty for violation of the Act. A copy of 45 C.F.R. Part 5b, Privacy Act Regulations, may be obtained at https://www.gpo.gov/fdsys/granule/CFR-2007- title45-vol1/CFR-2007-title45-vol1-part5b.

The Contractor is responsible for monitoring contractor compliance with the Privacy Act.

The Contractor shall follow the Privacy Act guidance as contained in the Privacy Act System of Records number 09-25-0200.

H.15 LABORATORY LICENSE REQUIREMENTS

The Contractor shall comply with all applicable requirements of Section 353 of the Public Health Service Act (Clinical Laboratory Improvement Act as amended) (42 U.S.C. 263a) and 42 CFR Part 493. This requirement shall also be included in any subcontract for services under the Contract.

H.16 QUALITY ASSURANCE (QA) AUDIT REPORTS

BARDA reserves the right to participate in QA audits as related to activities funded under this Contract. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.

- Contractor shall notify CO and COR of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications.
- Contractor shall notify the COR and CO within five (5) business days of report completion.

H.17 BARDA AUDITS

Contractor shall accommodate periodic or reasonable ad hoc site visits during normal business hours by the Government with forty-eight (48) hours advance notice. If the Government, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government.

- If issues are identified during the audit, Contractor shall submit a report to the CO and COR detailing the finding and corrective action(s) within 10 business days of the audit.
- COR and CO will review the report and provide a response to the Contractor with ten (10) business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

H.18 RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

The Contractor shall not use Contract funds to employ workers described in Section 274A (h)(3) of the Immigration and National Act, which reads as follows:

"(3) Definition of unauthorized alien – As used in this Section, the term 'unauthorized alien' with respect to the employment of an alien at a particular time, that the alien is not at that time either an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

H.19 NOTIFICATION OF CRITICAL PROGRAMMATIC CONCERNS, RISKS, OR POTENTIAL RISKS

If any action occurs that creates a cause for critical programmatic concern, risk, or potential risk to BARDA or the Contractor an Incident Report shall be delivered to BARDA.

- Within 48 hours of activity or incident or within 24 hours for a security related activity or incident, Contractor must notify BARDA.
- Additional updates due to COR and CO within 48 hours of additional developments.
- Contractor shall submit within 5 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues.

If corrective action is deemed necessary, Contractor must address in writing its consideration of concerns raised by BARDA within 5 business days of receiving comments by BARDA.

H.20 [Reserved]

H.21 DISSEMINATION OF INFORMATION (May 2004)

Other than scientific and technical data for which the Contractor can assert a copyright under FAR Clause 52.227-14 (c), no information related to data obtained under this Contract shall be released or publicized without the prior written consent of the CO. In the event that the Contractor seeks to publicize scientific and technical data, the contractor shall provide BARDA, through the COR, with a minimum of thirty (30) business days to review the particular scientific and technical data prior to publication.

H.22 REGISTRATION WITH THE SELECT AGENT PROGRAM FOR WORK INVOLVING THE POSSESSION, USE, AND/OR TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

Work involving select biological agents or toxins shall not be conducted under this Contract until the Contractor and any affected subcontractor(s) are granted a certificate of registration or are authorized to work with the applicable select agents.

For prime or subcontract awards to domestic institutions who possess, use, and/or transfer Select Agents under this contract, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), DHHS or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work involving Select Agents, in accordance with 42 C.F.R. Part 73. No Government funds can be used for work involving Select Agents, as defined in 42 C.F.R. Part 73, if the final registration certificate is denied.

For prime or subcontract awards to foreign institutions who possess, use, and/or transfer Select Agents under this Contract, the institution must provide information satisfactory to the Government that a process equivalent to that described in 42 C.F.R. Part 73 (http://www.cdc.gov/od/sap/docs/42cfr73.pdf) for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The Contractor must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 C.F.R. Part 73. The Government will assess the policies and procedures for comparability to the U.S. requirements described in 42 C.F.R. Part 73. When requested by the CO, the Contractor shall provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, the Contractor must provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents under the Contract.

Listings of HHS select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at https://www.selectagents.gov/

H.23 MANUFACTURING STANDARDS

The Good Manufacturing Practice Regulations (GMP) (21 C.F.R. Part 820) will be the standard to be applied for manufacturing, processing, packaging, storage and delivery of this product.

If at any time during the life of the Contract, the Contractor fails to comply with GMP in the manufacturing, processing, packaging, storage, stability and other testing of the manufactured drug substance or product and delivery of this product and such failure results in a material adverse effect on the safety, purity or potency of the product (a material failure) as identified by the FDA, the Contractor shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If, within the thirty (30) calendar day period, the Contractor fails to take such an action to the satisfaction of the Government Project Officer/COR, or fails to provide a remediation plan that is acceptable to the COR, then the Contract may be terminated.

H.24 LABORATORY LICENSE REQUIREMENTS

The Contractor shall comply with all applicable requirements of 21 C.F.R. Part 58 and FDA Medical Device GMP Guidance. This requirement shall also be included in any subcontract for services under the Contract.

H.25 SHARING RESEARCH DATA

The Contractor's data sharing plan, due date to be determined at contract award, is hereby incorporated by reference. The Contractor agrees to adhere to its plan and shall request prior approval of the CO for any changes in its plan.

BARDA endorses the sharing of final research data to serve health. This contract is expected to generate research data that must be shared with the public and other researchers.

BARDA recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Health Information Privacy at http://www hhs.gov/ocr/privacy/index.html). The rights and privacy of people who participate in BARDA-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

H.26 PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE (ASPR) FUNDED RESEARCH

All ASPR-funded investigators shall submit to the National Institutes of Health (NIH) National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, of any peer-reviewed scientific publications resulting from research supported in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response. ASPR defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and ASPR. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral nih.gov.

H.27 [Reserved]

H.28 [Reserved]

H.29 CLINICAL TERMS OF AWARD

In addition to those terms and conditions outlined under applicable HHSAR clauses incorporated by reference by Section I of this Contract, the following clinical terms of award detail an agreement between the BARDA and the Contractor; they apply to all contracts involving clinical research.

Draft protocols for each clinical study will be submitted to BARDA for evaluation and comment. BARDA comments will be addressed and/or incorporated into the draft protocol prior to submission to the FDA for comment, if required and as appropriate.

BARDA shall have unlimited rights to all protocols, data generated from the execution of these protocols, and final reports, funded by BARDA under this Contract, as defined in Rights in Data Clause in FAR 52.227-14. BARDA reserves the right to request that the Contractor provide any contract deliverable in a non-proprietary form without any restrictive legends to ensure BARDA has the ability to review and distribute the deliverables, as BARDA deems necessary.

Important information regarding performing human subject research is available here and should be addressed by the contractor. https://www hhs.gov/ohrp/

Any updates to clinical studies (enrollment, technical results, etc) are to be addressed in the Monthly and Annual Progress Reports, as well as technical monthly calls. The Contractor shall advise the COR or designee in writing and via electronic communication in a timely manner of any issues potentially affecting contract performance.

i. Safety and Monitoring Issues

a. Institutional Review Board or Independent Ethics Committee Approval

Before award and then with the annual progress report, the Contractor must submit to BARDA a copy of the current IRB-or IEC-approved informed consent document, documentation of continuing review and approval and the OHRP federal wide assurance number for the institution or site.

If other institutions are involved in the research (e.g., a multicenter clinical trial or study), each institution's IRB or IEC must review and approve the protocol. They must also provide BARDA initial and annual documentation of continuing review and approval, including the current approved informed consent document and federal wide number.

The Contractor must ensure that the application as well as all protocols are reviewed by their IRB or IEC.

To help ensure the safety of participants enrolled in BARDA-funded studies, the Contractor must provide BARDA copies of documents related to all major changes in the status of ongoing protocols, including the following:

- All amendments or changes to the protocol, identified by protocol version number, date, or both and dates it is valid.
- All changes in informed consent documents, identified by version number, dates, or both and dates it is valid.
- Termination or temporary suspension of patient accrual.
- Termination or temporary suspension of the protocol.
- Any change in IRB approval.
- Any other problems or issues that could affect the participants in the studies.

The Contractor must notify BARDA through the COR or CO of any of the above changes within five (5) working days by email or fax, followed by a letter signed by the institutional business official, detailing notification of the change of status to the local IRB and a copy of any responses from the IRB or IEC.

If a clinical protocol has been reviewed by an institutional biosafety committee (IBC) or the NIH Recombinant DNA Advisory Committee (RAC), the Contractor must provide information about the initial and ongoing review and approval, if any. See the NIH Guidelines for Research Involving Recombinant DNA Molecules.

b. Data and Safety Monitoring Requirements

BARDA strongly recommends independent safety monitoring for clinical trials of investigational drugs, devices, or biologics; clinical trial of licensed products; and clinical research of any type involving more than minimal risk to volunteers. Independent monitoring can take a variety of forms. Phase III clinical trials must be reviewed by an independent data and safety monitoring board (DSMB); other trials may require DSMB oversight as well. The Contractor shall inform BARDA of any upcoming site visits and/or audits of CRO facilities funded under this effort. BARDA reserves the right to accompany the Contractor on site visits and/or audits of CROs as BARDA deems necessary. The Contractor shall inform BARDA 30 days in advance of a DSMB board meetings for studies funded under this effort. BARDA reserves the right to participate in the DSMB board meetings on an impromptu basis as a non-voting member, if feasible per the structure of the study. If not, the communications from the DSMB to the Contractor should be made available to BARDA upon receipt.

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For examples, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of a routine physical examination (45 C.F.R. § 46.102(j)).

Final decisions regarding the type of monitoring to be used must be made by the Contractor, based on FDA and BARDA guidance, before enrollment starts. Discussions with the responsible BARDA PO/COR regarding appropriate safety monitoring must take place, and the Contractor must submit a written response to all concerns raised by BARDA, before patient enrollment begins and may include discussions about the appointment of one of the following:

Independent Safety Monitor – a physician or other appropriate expert who is independent of the study and available in real time to review and recommend appropriate action regarding adverse events and other safety issues.

Independent Monitoring Committee (IMC) or Safety Monitoring Committee (SMC) – a small group of independent investigators and biostatisticians who review data from a particular study.

Data and Safety Monitoring Board – an independent committee charged with reviewing safety and trial progress and providing advice with respect to study continuation, modification, and termination. The Contractor may use an established BARDA DSMB or to organize an independent DSMB. All phase III clinical trials must be reviewed by a DSMB; other trials may require DSMB oversight as well. Please refer to: NIAID Principles for Use of a Data and Safety Monitoring Board (DSMB) For Oversight of Clinical Trials Policy. BARDA should be provided documentation from DSMB and should be provided with any decisions by Contractor regarding the DMSB as it relates to work under this contract.

When a monitor or monitoring board is organized, a description of it, its charter or operating procedures (including a proposed meeting schedule and plan for review of adverse events), and roster and curriculum vitae from all members must be submitted to BARDA before enrollment starts. If concerns are raised, Contractor must address all concerns to BARDA, in writing, before enrollment begins. The Contractor will also ensure that the monitors and board members report any conflicts of interest and the Contractor will maintain a record of this. The Contractor will share conflict of interest reports with BARDA.

Additionally, the Contractor must submit written summaries of all reviews conducted by the monitoring group to the BARDA within thirty (30) days of reviews or meetings.

ii. BARDA Protocol Review Process Before Patient Enrollment Begins

BARDA has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in BARDA-supported clinical trials. Therefore, before patient accrual or participant enrollment, the Contractor must ensure the following (as applicable) are in place at each participating institution, prior to patient accrual or enrollment:

- IRB- or IEC-approved clinical research protocol identified by version number, date, or both, including details of study design, proposed interventions, patient eligibility, and exclusion criteria.
- Documentation of IRB or IEC approval, including OHRP federal wide number, IRB or IEC registration number, and IRB and IEC name.
- IRB- or IEC- approved informed consent form/document, identified by version number, date, or both and dates it is valid.
- Plans for the management of side effects.
- Procedures for assessing and reporting adverse events.
- Plans for data and safety monitoring (see above) and monitoring of the clinical study site, pharmacy, and laboratory.
- Documentation that the Contractor and all study staff responsible for the design or conduct of the research have received training in the protection of human subjects.

Documentation to demonstrate that each of the above items are in place shall be submitted to BARDA) for evaluation and comment in conjunction with the protocol. Execution of clinical studies requires written authorization from BARDA in accordance with this section of this contract.

iii. Investigational New Drug or Investigational Device Exemption Requirements

Consistent with federal regulations, applicable clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a FDA investigational new drug (IND) or investigational device exemption (IDE).

Where an IND and IDE is otherwise required, exceptions must be granted in writing by FDA. If the proposed clinical trial will be performed under an IND or IDE, the Contractor must provide BARDA with the name and institution of the IND or IDE sponsor, the date the IND or IDE was filed with FDA, the FDA IND or IDE number, any written comments from FDA, and the written responses to those comments.

In instances in which an IND or IDE is required, unless FDA notifies Contractor otherwise, the Contractor must wait thirty (30) calendar days from FDA receipt of an initial IND or IDE application before initiating a clinical trial.

The Contractor must notify BARDA if the FDA places the study on clinical hold and provide BARDA any written comments from FDA, written responses to the comments, and documentation in writing that the hold has been lifted.

The Contractor must not use grant or contract funds during a clinical hold to fund clinical studies that are on hold other than costs that are associated with activities related to patients coming off study, monitoring, or ending the study. The Contractor must not enter into any new financial obligations related to clinical activities for the clinical trial on clinical hold.

iv. Required Time-Sensitive Notification

a. Under an IND or IDE, the sponsor must provide FDA safety reports of serious adverse events. Under these Clinical Terms of Award, the Contractor must submit copies to the responsible BARDA representative or the COR as follows:

- Expedited safety report of unexpected or life-threatening experience or death. A copy of any report of unexpected or life-threatening experience or death associated with the use of an IND drug, which must be reported to FDA by telephone or fax as soon as possible but no later than seven (7) days after the IND sponsor's receipt of the information, must be submitted to BARDA representative or COR within 24 hours of FDA notification.

- Expedited safety reports of serious and unexpected adverse experiences. A copy of any report of unexpected and serious adverse experience associated with use of an IND drug or any finding from tests in laboratory animals that suggests a significant risk for human subjects, which must be reported in writing to FDA as soon as possible but no later than 15 days after the IND sponsor's receipt of the information, must be submitted to the BARDA representative or COR within 24 hours of FDA notification.

- IDE reports of unanticipated adverse device effect. A copy of any reports of unanticipated adverse device effect submitted to FDA must be submitted to BARDA representative or COR within 24 hours of FDA notification.

- Expedited safety reports. Sent to BARDA representative or the COR concurrently with the report to FDA.

- Other adverse events documented during the course of the trial should be included in the annual IND or IDE report and reported to BARDA annually.

b. Safety reporting for research not performed under an IND or IDE:

Final decisions regarding ongoing safety reporting requirements for research not performed under an IND or IDE must be made jointly by the BARDA PO or the COR and the Contractor.

In case of problems or issues the COR will contact the Contractor within ten (10) working days by email or fax, followed within thirty (30) calendar days by an official letter to the Contractor's Project Manager, with a copy to the institutions' office of sponsored programs, listing issues and appropriate actions to be discussed.

c. Human Material (Assurance of OHRP Compliance).

The acquisition and supply of all human specimen material (including fetal material) used under this Contract shall be obtained by Contractor in full compliance with applicable Federal, State and Local laws

and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this Contract, by collaborating sites, or by subcontractors identified under this Contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 C.F.R. 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by Contractor.

Provision by the Contractor to the CO of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self-designated form provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

PART II - CONTRACT CLAUSES

SECTION I – CONTRACT CLAUSES

I.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the CO will make their full text available. Also, the full text of a clause may be accessed electronically at: http://www.acquisition.gov/far. HHSAR clauses at http://www.hhs.gov/policies/hhsar/subpart352 html

General Clauses for a Firm Fixed Price Research and Development (R&D) Contract

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

Reg	Clause	Date	Clause Title
FAR	52.202-1	Nov 2013	Definitions
FAR	52.203-3	Apr 1984	Gratuities
FAR	52.203-5	May 2014	Covenant Against Contingent Fees
FAR	52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government
FAR	52.203-7	May 2014	Anti-Kickback Procedures
FAR	52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity
FAR	52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity
FAR	52.203-11	Sept 2007	Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions
FAR	52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions
FAR	52.203-13	Oct 2015	Contractor Code of Business Ethics and Conduct
FAR	52.203-14	Oct 2015	Display of Hotline Poster(s)
FAR	52.203-17	Apr 2014	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights
FAR	52.203-19	Jan 2017	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements
FAR	52.204-1	Dec 1989	Administrative Matters Provisions and Clauses
FAR	52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper
FAR	52.204-7	Jul 2016	System for Award Management
FAR	52.204-8	Oct 2018	Annual Representations and Certifications
FAR	52.204-10	Oct 2016	Reporting Executive Compensation and First-Tier Subcontract Awards
FAR	52.204-13	Oct 2016	System for Award Management Maintenance
FAR	52.204-16	Jul 2016	Commercial and Government Entity Code Reporting.
FAR	52.204-18	Jul 2016	Commercial and Government Entity Code Maintenance
FAR	52.204-19	Dec 2014	Incorporation by Reference of Representations and Certifications
FAR	52.204-23	Jul 2018	Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities
FAR	52.204-25	Aug 2019	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment

FAR	52.207-1	May 2006	Notice of Standard Competition
FAR	52.209-6	Oct 2015	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment
FAR	52.209-9	Jul 2013	Updates of Publicly Available Information Regarding Responsibility Matters
FAR	52.209-10	Nov 2015	Prohibition on Contracting with Inverted Domestic Corporations
FAR	52.210-1	Apr 2011	Market Research
FAR	52.215-2	Oct 2010	Audit and Records – Negotiation
FAR	52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
FAR	52.215-14	Oct 2010	Integrity of Unit Prices (Over the Simplified Acquisition Threshold
FAR	52.215-22	Oct 2009	Limitations on Pass-Through Charges—Identification of Subcontract Effort
FAR	52.215-23	Oct 2009	Limitations on Pass-Through Charges
FAR	52.219-8	Oct 2014	Utilization of Small Business Concerns
FAR	52.219-28	Jul 2013	Post-Award Small Business Program Representation
FAR	52.222-21	Apr 2015	Prohibition of Segregated Facilities
FAR	52.222-25	Apr 1984	Affirmative Action Compliance
FAR	52.222-35	Oct 2015	Equal Opportunity for Veterans ($150,000 or more)
FAR	52.222-36	Jul 2014	Equal Opportunity for Workers with Disabilities
FAR	52.222-37	Feb 2016	Employment Reports on Veterans
FAR	52.222-38	Feb 2016	Compliance with Veterans' Employment Reporting Requirements
FAR	52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act
FAR	52.222-41	Aug 2018	Service Contract Labor Standards.
FAR	52.222-50	Mar 2015	Combating Trafficking in Persons
FAR	52.222-54	Oct 2015	Employment Eligibility Verification
FAR	52.223-6	May 2001	Drug-Free Workplace
FAR	52.223-18	Aug 2011	Encouraging Contractor Policy to Ban Text Messaging While Driving
FAR	52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
FAR	52.225-25	Oct 2015	Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran—Representation and Certifications
FAR	52.226-1	Jun 2000	Utilization of Indian Organizations and Indian-Owned Economic Enterprises.
FAR	52.227-1	Dec 2007	Authorization and Consent, Alternate 1 (APR 1984)
FAR	52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
FAR	52.227-3	Apr 1984	Patent Indemnity ALT 1
FAR	52.227-11	May 2014	Patent Rights – Ownership by the Contractor
FAR	52.227-14	May 2014	Rights in Data – General
FAR	52.227-15	Dec 2007	Representation of Limited Rights Data and Restricted Computer Software
FAR	52.227-16	June 1987	Additional Data Requirements

FAR	52.228-7	Mar 1996	Insurance – Liability to Third Persons
FAR	52.229-3	Feb 2013	Federal, State, and Local Taxes.
FAR	52.232-2	Apr 1984	Payments Under Fixed-Price Research and Development Contracts
FAR	52.232-20	Apr 1984	Limitation of Cost
FAR	52.232-23	May 2014	Assignment of Claims
FAR	52.232-25	Jan 2017	Prompt Payment
FAR	52.232-33	Jul 2013	Payment by Electronic Funds Transfer–System for Award Management
FAR	52.232.39	Jun 2013	Unenforceability of Unauthorized Obligations
FAR	52.232-40	Dec 2013	Providing Accelerated Payments to Small Business Subcontractors
FAR	52.233-1	May 2014	Disputes
FAR	52.233-2	Sep 2006	Service of Protest
FAR	52.233-3	Aug 1996	Protest After Award
FAR	52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
FAR	52.242-1	Apr 1984	Notice of Intent to Disallow Costs
FAR	52.242-3	May 2014	Penalties for Unallowable Costs
FAR	52.242-4	Jan 1997	Certification of Final Indirect Costs
FAR	52.242-13	Jul 1995	Bankruptcy
FAR	52.242-15	Aug 1989	Stop Work Order
FAR	52.243-1	Aug 1984	Changes – Fixed Price Alternate V
FAR	52.244-2	Oct 2010	Subcontracts, Alternate 1 (Jun 2007)
FAR	52.244-5	Dec 1996	Competition in Subcontracting
FAR	52.244-6	Jan 2019	Subcontracts for Commercial Items
FAR	52.245-1	Apr 2012	Government Property
FAR	52.245-9	Apr 2012	Use and Charges
FAR	52.246-4	Aug 1996	Inspection of Services -- Fixed-Price
FAR	52.246-7	Aug 1996	Inspection of Research and Development -- Fixed-Price
FAR	52.246-9	Aug 1989	Inspection of Research and Development (Short Form)
FAR	52.246-16	Aug 1984	Responsibility for Supplies
FAR	52.246-23	Feb 1997	Limitation of Liability
FAR	52.249-2	Apr 2012	Termination for Convenience of the Government (Fixed-Price)
FAR	52.249-9	Apr 1984	Default (Fixed-Price Research and Development)
FAR	52.253-1	Jan 1991	Computer Generated Forms

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

Reg	Clause	Date	Clause Title
HHSAR	352.203-70	Dec 2015	Anti-Lobbying
HHSAR	352.208-70	Dec 2015	Printing and Duplication
HHSAR	352.211-3	Dec 2015	Paperwork Reduction Act
HHSAR	352.222-70	Dec 2015	Contractor Cooperation in Equal Employment Opportunity Investigations
HHSAR	352.223-70	Dec 2015	Safety and Health
HHSAR	352.224-70	Dec 2015	Privacy Act
HHSAR	352.224-71	Dec 2016	Confidential Information

HHSAR	352.227-70	Dec 2015	Publications and Publicity
HHSAR	352.233-70	Dec 2015	Choice of Law (Overseas)
HHSAR	352.237-75	Dec 2015	Key Personnel
HHSAR	352.231-70	Dec 2015	Salary Rate Limitation
HHSAR	352.239-74	Dec 2015	Electronic and Information Technology Accessibility
HHSAR	352.270-5b	Dec 2015	Care of Live Vertebrate Animals.
HHSAR	352.270-6	Dec 2015	Restriction on Use of Human Subjects.
HHSAR	352.270-9	Dec 2015	Non-discrimination for Conscience
HHSAR	352.270-13	Dec 2015	Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research.

I.2. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

This contract incorporates the following clauses in full text. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

FAR Clause 52.219-28, Post-Award Small Business Program Representation (July 2013)

a. *Definitions* . As used in this clause--

Long-term contract means a contract of more than five years in duration, including options. However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-8, Option to Extend services, or other appropriate authority.

Small business concern means a concern, including its affiliates that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause. Such a concern is "not dominant in its field of operation" when it does not exercise a controlling or major influence on a national basis in a kind of business activity in which a number of business concerns are primarily engaged. In determining whether dominance exists, consideration shall be given to all appropriate factors, including volume of business, number of employees, financial resources, competitive status or position, ownership or control of materials, processes, patents, license agreements, facilities, sales territory, and nature of business activity.

b. If the Contractor represented that it was a small business concern prior to award of this contract, the Contractor shall re-represent its size status according to paragraph (e) of this clause or, if applicable, paragraph (g) of this clause, upon the occurrence of any of the following:

(1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts--

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and
(ii) Within 60 to 120 days prior to the date specified in the contract for exercising any option thereafter.

c. The Contractor shall represent its size status in accordance with the size standard in effect at the time of this re-representation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at http://www.sba.gov/content/table-small-business-size-standards

d. The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.

e. Except as provided in paragraph (g) of this clause, the Contractor shall make the representation required by paragraph (b) of this clause by validating or updating all its representations in the Representations and Certifications Section of the System for Award Management (SAM) and its other data in SAM, as necessary, to ensure that they reflect the Contractor's current status. The Contractor shall notify the contracting office in writing within the timeframes specified in paragraph (b) of this clause that the data have been validated or updated, and provide the date of the validation or update.

f. If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

g. If the Contractor does not have representations and certifications in SAM, or does not have a representation in SAM for the NAICS code applicable to this contract, the Contractor is required to complete the following representation and submit it to the contracting office, along with the contract number and the date on which the representation was completed:

The Contractor represents that it **X is, [ ] is not** a small business concern under NAICS Code 541715 assigned to this contract.

(End of clause)

FAR 52.204-21 Basic Safeguarding of Covered Contractor Information Systems (Jun 2016)

(a) *Definitions*. As used in this clause--

“Covered contractor information system” means an information system that is owned or operated by a contractor that processes, stores, or transmits Federal contract information.

“Federal contract information” means information, not intended for public release, that is provided by or generated for the Government under a contract to develop or deliver a product or service to the Government, but not including information provided by the Government to the public (such as on public Web sites) or simple transactional information, such as necessary to process payments.

“Information” means any communication or representation of knowledge such as facts, data, or opinions, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual (Committee on National Security Systems Instruction (CNSSI) 4009).

“Information system” means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information (44 U.S.C. 3502).

“Safeguarding” means measures or controls that are prescribed to protect information systems.

(b) Safeguarding requirements and procedures.

(1) The Contractor shall apply the following basic safeguarding requirements and procedures to protect covered contractor information systems. Requirements and procedures for basic safeguarding of covered contractor information systems shall include, at a minimum, the following security controls:

(i) Limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems).
(ii) Limit information system access to the types of transactions and functions that authorized users are permitted to execute.
(iii) Verify and control/limit connections to and use of external information systems.
(iv) Control information posted or processed on publicly accessible information systems.
(v) Identify information system users, processes acting on behalf of users, or devices.
(vi) Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.
(vii) Sanitize or destroy information system media containing Federal Contract Information before disposal or release for reuse.
(viii) Limit physical access to organizational information systems, equipment, and the respective operating environments to authorized individuals.
(ix) Escort visitors and monitor visitor activity; maintain audit logs of physical access; and control and manage physical access devices.
(x) Monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems.
(xi) Implement subnetworks for publicly accessible system components that are physically or logically separated from internal networks.
(xii) Identify, report, and correct information and information system flaws in a timely manner.
(xiii) Provide protection from malicious code at appropriate locations within organizational information systems.
(xiv) Update malicious code protection mechanisms when new releases are available.
(xv) Perform periodic scans of the information system and real-time scans of files from external sources as files are downloaded, opened, or executed.

a. *Other requirements*. This clause does not relieve the Contractor of any other specific safeguarding requirements specified by Federal agencies and departments relating to covered contractor information systems generally or other Federal safeguarding requirements for controlled unclassified information (CUI) as established by Executive Order 13556.

(c) *Subcontracts*. The Contractor shall include the substance of this clause, including this paragraph (c), in subcontracts under this contract (including subcontracts for the acquisition of commercial items, other than commercially available off-the-shelf items), in which the subcontractor may have Federal contract information residing in or transiting through its information system.

(End of clause)

FAR 52.227-7 Patents – Notice of Government License (APR 1984)

The Government is obligated to pay a royalty applicable to the proposed acquisition because of a license agreement between the Government and the patent owner. The patent number is ____ [Contracting Officer fill in], and the royalty rate is ____ [Contracting Officer fill in]. If the offeror is the owner of, or a licensee under, the patent, indicate below:

☐ **Owner**
☐ **Licensee**

If an offeror does not indicate that it is the owner or a licensee of the patent, its offer will be evaluated by adding thereto an amount equal to the royalty

(End of clause)

I.2. ADDITIONAL HHSAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

HHSAR 352.231-70 – Salary Rate Limitation (December 18, 2015)

i. Pursuant to the current and applicable prior HHS appropriations acts, payment of the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date Government funding was obligated.

ii. For purposes of the salary rate limitation, the terms "direct salary," "salary", and "institutional base salary", have the same meaning and are collectively referred to as "direct salary", in this clause. An individual's direct salary is the annual compensation that the Recipient pays for an individual's direct effort (costs) under the contract. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Recipient. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative [F&A] costs).

Note: The salary rate limitation does not restrict the salary that an organization may pay an individual working under a Government contract, order, or OTAR; it merely limits the portion of that salary that may be paid with Federal funds.

iii. The salary rate limitation also applies to individuals under Sub-Recipient Agreements except to the extent that that a Sub-Recipient Agreement is awarded on a fixed-price basis without analysis of labor costs. If this is a multiple-year contract, it may be subject to unilateral modification by the CO to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act in effect when the expense is incurred regardless of the rate initially used to establish Agreement funding.

iv. See the salaries and wages pay tables on the U.S. Office of Personnel Management Web site for Federal Executive Schedule salary levels that apply to the current and prior periods

(End of clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Statement of Work, dated 19 March 2020
2. Sample Invoice/Financial Request Instructions
3. Schedule of Payments

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

The following documents are incorporated by reference in this contract:

a. Animal Research Assurance Identification Numbers: To be provided prior to study execution.
b. Human Subjects Assurance Identification Numbers: To be provided prior to study execution.

Pursuant to 45 CFR part 46, Protection of Human Research Subjects, the Contractor shall not expend funds under this award for research involving human subjects or engage in any human subject research activity prior to the Contracting Officer's receipt of a certification that the research has been reviewed and approved by the Institutional Review Board (IRB) registered with OHRP. This restriction applies to all collaborating sites, whether domestic or foreign, and subcontractors. The Contractor must ensure compliance by collaborators and subcontractors.

Attachment 1

Biomedical Advanced Research and Development Authority (BARDA)
Broad Agency Announcement BAA-20-100-SOL-0002

GenMark Dx ePlex® Respiratory
Pathogen v2 Panel
Area of Interest #4.1-A (COVID-19)

Statement of Work (SOW)

PREAMBLE

Independently, and not as an agent of the government, the contractor shall furnish all necessary services; qualified professional, technical, and administrative personnel; and material, equipment, and facilities not otherwise provided by the government under the terms of this contract, as needed to perform the tasks set forth below.

The government reserves the right to modify the budget, progress, schedule, or milestones to add or delete processes, schedules, or deliverables if the need arises. Because of the nature of this research and development (R&D) contract and the complexities inherent in this and prior programs, at designated milestones the government will evaluate whether work should be redirected or removed, or whether schedule or budget adjustments should be made. The government reserves the right to change the product, process, schedule, or events to add or delete part or all of these elements as the need arises.

Overall Objectives and Scope

The overall objective of this contract is to develop an updated and expanded version of the ePlex Respiratory Pathogen (RP) Panel to include assays for the detection of SARS-CoV-2 in upper respiratory tract specimens, referred to in the remainder of the document as ePlex RP v2 panel. The Design Verification and Validation Plan and subsequent testing will be used to address all the studies required to support the regulatory submission(s) to FDA for the indication of Emergency Use Authorization of the ePlex RP Panel v2.

The scope of work for this contract includes incorporation of the assays of the EUA (*submitted*) ePlex SARS-CoV-2 Test, previously developed as a single target test cartridge, into an expanded version of the existing ePlex RP v1 Panel, which is a highly multiplexed FDA 510(k)-cleared diagnostic test. The ePlex RP v1 Panel is a comprehensive test that identifies and detects the most common viral and bacterial organisms causing respiratory illness and including SARS-CoV-2 on this panel will streamline detection and identification and enable clinicians to optimize patient care based on the pathogen detected. Development to include SARS-CoV-2 as a target on the ePlex RP v1 Panel is expected to require a minimum of 6-9 months of work (to be completed by December 2020). While initial development demonstrated that the SARS-CoV-2 assay is sensitive and specific for its intended target, this work will focus on optimizing the performance of this test in combination with more than 20 other assays for additional targets. Once the ideal testing parameters have been identified, performance will be formally verified with analytical and clinical studies sponsored by GenMark. The FDA-510(k)-cleared targets on the currently marketed ePlex Respiratory Pathogen Panel are provided in Table 1.

Table 1. Current ePlex Respiratory Pathogen Panel (v1)

VIRAL TARGETS	
Adenovirus	Coronavirus (229E, HKU1, NL63, OC43)
Human Metapneumovirus	Human Rhinovirus/Enterovirus
Influenza A	Influenza A H1
Influenza A H1-2009	Influenza A H3
Influenza B	Parainfluenza 1
Parainfluenza 2	Parainfluenza 3
Parainfluenza 4	Respiratory Syncytial Virus A
Respiratory Syncytial Virus B	
BACTERIAL TARGETS	
Mycoplasma pneumoniae	*Chlamydia pneumoniae*

The R&D effort for **GenMark ePlex Respiratory Pathogen v2 Panel** will progress in work segments with key Deliverables being due during the Base Period of performance of the contract (the Base Period will be labeled Contract Line Item Number (CLIN) 0001). Each Deliverable will require a concrete work segment with a well-defined objective, scope of work, and success metric for accomplishing the Deliverable. The work segments for each Deliverable may occur sequentially or simultaneously based on the pathway and needs of the project.

In addition to the requirements outlined under "Section F.2 Deliverables" of the contract, the following deliverables are defined for this project:

1. **Deliverable 1 –** Project Plan
2. **Deliverable 2 –** Feasibility and Development
3. **Deliverable 3 –** Verification/Validation and Clinical Study

1. Deliverable 1: Project Plan

Objective:
To detail the project plan in accordance with the GenMark Design and Development Plan for all projects operating under the Design Control Procedure. The plan will outline the goals, deliverables, and intended pathway for the project, including a Gantt Chart, Risk Management Plan, and tools/techniques used to track and monitor the cost and schedule of the project.

Scope of Work:
The Assay Development Project Manager will establish the design and development plan and communicate the plan to the Product Approval Committee (PAC). The purpose of the Respiratory Panel v2 Design and Development Plan (DDP) is to identify, manage and control the product development and commercialization activities for the product. This DDP shall cover the activities associated with the development and market release of the RP v2 Panel and the associated deliverables. The activities include all elements of:

- Design Control (Planning, Design Input, Design Output, Design Reviews, Design Verification, Design Validation, and Design Transfer)
- Project Timeline
- Organizational Interfaces
- Regulatory Plan

The Project Manager will be responsible for managing the master schedule, tracking major project deliverables, and scheduling appropriate reviews. This work will be to establish and update (as needed) the project timeline and ensure the timely completion of project deliverables; to provide risk assessment and communicate critical issues impacting product quality to management; to ensure that participants at each Design Review include representatives from all functions concerned with the design stage being reviewed; to communicate the progress and status of the project to the Core Team through meetings, meeting notes and/or email; and create and maintain the Design History File (DHF).

The development and commercialization of this project will be performed in multiple phases. The different components encompassed within this project may enter into the various phases of development at different times. Design validation and verification activities will be separated where needed to accommodate this plan. Reviews for design and development activities in support of this project will be scheduled as needed and may overlap, be combined, or delayed as needed to meet the requirements of each phase of the project. Reviews may include technical review, review of project status, project risk evaluation, Product Approval Committee (PAC) review and approval, or any combination of these and additional elements. Multiple reviews for different elements of a single milestone may be scheduled at different times to meet the requirements of a project phase. These reviews will be scheduled and combined as needed and will be tracked on the Project Schedule.

A cross-functional Core Team with representatives from appropriate departments will be assigned to the project. Additional support will be obtained as needed. The Core Team members will be assigned per the Design Control Quality Procedure. In some instances, a Core Team member may represent more than one organizational area.

The activities required for the project will be identified in the Project Deliverables
List of the DDP and documents will be filed in the Design History File upon delivery. The members of the Core Team will be identified and tracked. The tracking document will be updated as needed throughout the duration of the project. The DDP and Project Schedule will be used to communicate the scope and status of the project. The Core Team will meet informally to manage the

details of the project and drive research, development, and tactical actions. These informal meetings will not require formal documentation, nor do they require full Core Team representation at each meeting. However, if a significant issue impacting product design or planning is raised or resolved at such a meeting, the meeting will be documented as a Key Meeting in meeting minutes and filed in the DHF.

Success Metric for Completion of Deliverable 1:
The completion and approval by Project Approval Committee (PAC) of an ePlex RP v2 Panel for the inclusion of the SARS-CoV-2 assay Design and Development Plan (DDP) that will serve as the project plan. The completion of a Risk Management Plan with input from the project Core Team.

2. **Deliverable 2: Feasibility and Development**

Objective:
To demonstrate the feasibility of adding the SARS-CoV-2 assay to the existing ePlex Respiratory Pathogen Panel cartridge that includes the previously characterized, FDA-cleared pathogen targets and optimize the performance of this test in combination with the more than 20 other assays on the panel.

Scope of Work:
For the scope of this deliverable, the distinct phases of Feasibility (CP1) and Planning & Development (CP2) of the GenMark product development process will be combined into a single deliverable. Intent of the Feasibility phase will be to execute the feasibility study plan/report for the addition of the SARS-CoV-2 assays to the existing RP v1 panel while still meeting the established requirements of the RP Panel Design (DRD), Product (PRD) and Market Requirements (MR).

The purpose of the feasibility study plan will entail all R&D activities and testing required to optimize the inclusion of the SARS-CoV-2 Wuhan-2 and Wuhan-3 assays on the current ePlex RP v1 consumable using dried reagents at the limit of detection for the assay targets. The intent will be to demonstrate feasibility of sample processing through detection on the ePlex RP consumable by adding the Wuhan-2 and Wuhan-3 primer and probes to the regions with area available for additional multiplex reactions on the consumable (Figure 1) while taking into consideration the performance of the existing amplification and detection reactions so as not to impact any established performance characteristics. An assessment of performance of all RP v1 Panel targets and the Wuhan-2 and Wuhan-3 assays will be performed and based on acceptance criteria the formulation will be locked or the location will be changed until the optimal performance and sensitivity of the Wuhan-2 and Wuhan-3 SARS-CoV-2 assays is reached. Once the optimal performance is achieved the design and formulation of RP v2 will be locked.

(b) (4)

Acceptance criteria for the RP v2 design will be:

Category	Requirement
Accuracy	Have a PPA and NPA of >90% compared to the ePlex SARS-CoV-2 Assay.
Analytical Sensitivity and Specificity	Have analytical sensitivity and specificity equivalent to (within 1 log or better) than the ePlex SARS-CoV-2 consumable.
	The Assay shall detect SARS-CoV-2 in a mixed infection with viral pairs at 1x LoD and 10^5 copies/mL or $TCID_{50}$/ml in the same sample, bacterial pairs at 10^6 CFU/ml in the same sample or a combination of virus and bacteria.
Cross-reactivity	The Assay shall not cross-react with other organisms of similar or shared sequence homology or with viral types, viral sub-types, or bacteria on the panel.

And, no changes should be observed for the following ePlex RP v1 product requirements:

1. The Assay shall detect, at a minimum, the same organisms for aliquots of samples stored at different conditions.
2. Time to result for the consumable should remain the same at ≤102 minutes (on average) from start to end.
3. No impact to the on-consumable assay controls.

Success Metric for Completion of Deliverable 2:

Assay formulation lock and the completion of all Design Control deliverables required for Phase 1 and 2 must by verified. Satisfaction of the acceptance of the criteria established for this milestone as part of the required Phase Gate Review by the Management Review team (PAC).

Completion and approval of the following documents:

- Market Requirements Document (MRD)
- Product Requirements Document (PRD)
- Software Requirements Document (SRS)

- Marketing Plan
- Requirement Traceability Matrix
- Verification & Validation Plan
- Service and Support Plan
- Team Planning & Development Phase Review Records
- PAC Planning & Development Phase Review Records
- DHF Master index

3. Deliverable 3: Verification/Validation and Clinical Study

Objective:
To verify and or validate the performance of the addition of the SARS-CoV-2 assay to the ePlex Respiratory Pathogen Panel version 2 on the ePlex Instrument. The Design Verification and Validation testing shall be performed in accordance with the quality work instructions set forth by GenMark in order to provide objective evidence that the device requirements for a specific intended use by the intended user can be consistently fulfilled in accordance with claims and labeling in a clinical user/setting. The Design Verification and Validation Plan and subsequent testing will be used to address all the studies required to support the regulatory submission(s) to FDA for Emergency Use Authorization.

Scope of Work:

Design Verification and Validation
The Research and Development team shall perform design verification and validation activities at the system level for the assay to confirm by objective evidence that the design output meets the design input product requirements (PRD). The design verification testing will be performed in accordance with the Quality System specifications and the requirements specified in the PRD and Design Verification and Validation Test Plan. Assay specific verification studies will be detailed in the Assay Verification Plan(s) and filed in the Design History File. The Verification and Validation Plan(s) outlines the verification work of all PRD, Design Requirements Documents (DRD), and Software Requirement Specifications (SRS) requirements to be complete. Pilot product lots will be used during the Design Verification activities. Defects found during the design verification testing activities will be documented in the defect tracking system for investigation and resolution. The Core Team will determine the disposition of the defect(s). The data from the testing will be presented to the Core Team for review and approval. Technical Design Reviews will be conducted throughout the project. During Design Verification, mitigation of identified hazards in the risk analysis will be verified.

An RP v2 Assay Verification and Validation Plan will describe the verification and validation activities planned and owners of those activities. There will be a Software Verification and Validation Plan describing the activities planned for the assay specific software. Code Reviews will be conducted to ensure the software specifications are satisfied in accordance with the Software Requirements Specifications. For Verification Testing, requirements will be used to generate a set of acceptance criteria for the approved test protocols. The approved test protocols will be used to execute testing. The objective evidence will be generated and analyzed against acceptance criteria to determine if product meets the PRD and the SRS documents. Testing for Design Verification should verify safety, performance, and reliability under simulated use conditions. Assay Verification Report(s) and the Software Verification Report will report the results of verification testing and document the objective evidence that the criteria outlined in the test protocol and PRD were met. Verification Summary Reports will be written to summarize the results from all verification studies.

The following describes the testing that will be performed to address the addition of the SARS-CoV-2 assays

to the existing ePlex Respiratory Pathogen Panel to support the regulatory submission(s) of the ePlex RP v2 Panel for Emergency Use Authorization.

1. **Analytical Sensitivity (Limit of Detection)**
    a. Scope: Evaluate the performance of the addition of the SARS-CoV-2 Assay with respect to sensitivity on the Respiratory Pathogen v2 Panel. Analytical sensitivity for RP v2 will be verified.
        i. Serial dilutions of the viral *in vitro* transcript (IVT) will be prepared at seven concentrations and tested in a minimum of three replicates. The test concentrations will be chosen based on data gathered during the product development for the ePlex SARS-CoV-2 Assay. Testing will use samples spiked with the viral RNA IVT at 2 logs above, 1 log above, at 1 log below and 2 logs below the expected LoD. PBS buffer will be used as the negative matrix to minimize degradation of the IVT.
    b. Acceptance Criteria: The preliminary LoD will be determined as the lowest dilution at which 95% of replicates are detected. The lowest concentration that resulted in 95% positive results will be tested in the LoD verification.
2. **Limit of Blank**
    a. Scope: Verify that negative samples provide low/no signal.
        i. The LoB will be estimated from repeated measurements of several blank samples. The blank samples will be derived from negative simulated sample matrix The experimental design will include a minimum of 60 blank replicate measurements, as well as a minimum of four negative clinical nasopharyngeal swab (NPS) samples or sample pools, using two lots of consumables.
    b. Acceptance Criteria: Negative samples should contain signal that is lower than threshold or no signal in ≥95% of samples tested.

3. **Cut-Off Analysis**
    a. Scope: Define cut off value for the SARS-CoV-2 analyte.
        i. The assay cut-offs for the SARS-CoV-2 analyte will be defined empirically using a minimum of 300 specimens comprising a combination of negative and positive clinical specimens and contrived positive samples and will be verified based on Receiver Operating Curve (ROC) analysis. Data generated from the LoD and LoB studies will be utilized.
    b. Acceptance Criteria: The assay cut-off for the SARS-CoV-2 analyte is defined by having a defined signal boundary. The assay boundary value will be calculated for each target using the combined data sets. The calculated value should be consistent with the expected call (Detected/Not Detected).

4. **Analytical Reactivity (Inclusivity)**
    a. Scope: Evaluate the performance of the SARS-CoV-2 analyte on the RP v2 Panel with respect to inclusivity of isolates.
        i. Commercially available genomic RNA and primary specimens in our biorepository will be utilized. Simulated reactivity for those strains not in circulation has been performed as part of the development of the ePlex SARS-CoV-2 Assay. The Analytical Reactivity will be initially determined near the LoD (3x LoD). Each strain will be spiked into pooled negative NPS at 3x LoD and tested in triplicate. These will be quantified by a well-qualified RT-PCR method (with confirmation by bi-directional sequencing if necessary)

and diluted to a concentration of 3x the LoD. If any strains are unavailable, *in silico* analysis will be performed to obtain simulated reactivity data.

b. Acceptance Criteria: The SARS-CoV-2 analyte will produce a positive result for all the samples tested above the limit of detection of the assay as defined by analytical reactivity.

5. Cross Reactivity/Exclusivity

a. Scope: Evaluate cross reactivity of viral, bacterial or fungal strains with ePlex RP v2 Panel SARS-CoV-2 analyte.

i. This study will evaluate performance of the ePlex RP v2 Panel in the presence of high concentrations of on-panel and off-panel analytes. Each analyte will be tested in triplicate using simulated viral or bacterial samples at a high concentration ($1x10^5$ copies/mL of IVT, $1x10^5$ $TCID_{50}$/mL for viruses and $1x10^6$ CFU/mL for bacteria and fungi). Cross-reactivity will be assessed by analyzing the positive calls and signals for the expected analyte on the expected electrodes.

b. Acceptance Criteria: 100% concordance with expected results.

6. Interfering Substances

a. Scope: Verify that potentially co-existing microorganisms or interfering substances in the specimens will not interfere with the performance of the SARS-CoV-2 analyte.

i. Performance of the ePlex RP v2 Panel SARS-CoV-2 analyte will be evaluated by conducting a comprehensive interference study using medically relevant concentrations of common interfering substances. SARS-CoV-2 known positive material will be spiked into Viral Transport Media (VTM) near the LoD and tested with and without the presence of many common interfering substances. Each potentially interfering substance will be added to the simulated sample and tested in triplicate. The positive call rate in the presence of each potential interfering substance will be analyzed.

b. Acceptance Criteria: 100% concordance with expected results.

7. Reproducibility Study

a. Scope: Determine the SARS-CoV-2 assay reproducibility on the ePlex RP v2 Panel. Provide the appropriate data to support the reproducibility of the samples tested.

i. Reproducibility and lot-to-lot variability will be assessed. A total of 108 replicate tests will be performed for the SARS-CoV-2 analyte/concentration (3 sites x 2 operators per site x 6 testing days x 3 replicates per analyte/concentration). The testing will consist of multiple representative analytes at 3 testing concentrations: moderate positive (3x LoD), low positive (1x LoD), and negative (100% negative). Positive samples will consist of viral transport media spiked with virus, bacteria or IVT. Negative samples will consist of clinical specimens that test negative for the SARS-CoV-2 analyte or simulated sample matrix. The sample panel will be tested with 3 lots of consumables, at each of three sites by two operators per site and with 1 instrument per site. Each site will perform multiple runs over multiple days. At each site, operators will run two sets of samples in triplicate as blinded samples on 6 testing days (at least 5 on alternating/non-consecutive days), such that no one operator tests the same sample on consecutive testing days.

b. Acceptance Criteria: 95% concordance with expected results.

8. Clinically Relevant Coinfections (Dual Co-Infection)

a. Scope: Evaluate competitive inhibition due to clinical co-infection of on-panel and off-

panel organisms

i. The study will employ limiting dilutions of grown and titered viral and bacterial reference strains. The proposed study will test for detection of clinically relevant co-infections at LoD and at high titer ($1x10^5$ copies/mL of IVT, $1x10^5$ $TCID_{50}$/mL for viruses and $1x10^6$ CFU/mL for bacteria and fungi).

b. Acceptance Criteria: 100% concordance with expected results.

9. Carryover & Cross Contamination

a. Scope: Evaluate the performance of the RP v2 Panel with respect to carryover and cross contamination.

i. Carryover and cross-contamination testing will consist of alternating "high positive" sample with SARS-CoV-2 and "true negative" samples within a study run. Negative sample matrix will be used for both positive and negative samples. Simulated matrix samples of VTM spiked with SARS-CoV-2 at a concentration of 1 x 10^5 copies/mL will be tested alongside simulated negative samples (VTM). Each run will consist of 12 replicates of each sample (negative, and SARS-CoV-2 at 1 x 10^5 copies/mL) prepared and tested in an alternating fashion for a total of 24 RP v2 panel tests per run. For each run, all 24 tests will be performed at the same time using a single instrument, alternating positive and negative samples tested in the same bay of the instrument. The study will contain a total of 5 identical runs executed over a period of 5 days. The data will be analyzed for the percentage of correct calls (Detected for SARS-CoV-2 samples or Not Detected for "true negative" samples).

b. Acceptance Criteria: 100% concordance with expected results.

10. Fresh vs. Frozen Study

a. Scope: Establish performance in frozen samples.

i. A panel of samples will be prepared that includes the SARS-CoV-2 analyte, which is spiked into negative sample matrix at a specific concentration (1x LoD). Samples will be stored frozen and subjected to one or two freeze/thaw cycles prior to testing. Results of the frozen samples will be compared to samples that are tested fresh.

b. Acceptance Criteria: Equivalent performance between the fresh and frozen conditions.

11. Sample Matrix Equivalency Study

a. Scope: Evaluate sample matrix equivalency between commercially available VTM and nasopharyngeal swabs (NPS) collected in for the RP ePlex assays.

i. The sample matrix equivalency study will compare the performance of the SARS-CoV-2 analyte spiked near LoD into VTM, as well as into 100 individual clinical NPS samples collected in VTM. Each spiked sample in VTM and NPS will be tested in two replicates. The positive call rate for all spiked samples will be analyzed and compared between the two matrices.

b. Acceptance Criteria: 100% concordance with expected results.

12. Control Effectiveness Study

a. Scope: Outline the procedure for testing the potential impact of different failure modes on the performance of the two different internal controls in the ePlex RP v2 Panel.

i. The targets that are detected on the ePlex RP v2 Panel are amplified in several

different pools. Each of these pools also amplifies one or more of the Internal Controls, either the RNA Positive Control or the Extraction Control. The SARS-CoV-2 analyte will be spiked into each individual sample and diluted to the testing concentration of 10x LoD. Each sample will be tested in triplicate on the ePlex instrument.

b. Acceptance Criteria: All of the analytes in the control condition at approximately 10x LoD shall yield a positive result in all triplicates tested if the run is valid. If any of the analytes in the control does not yield a positive result in a valid run, an investigation will be performed.

Clinical Studies

The purpose of the study will be to establish the clinical performance characteristics of the ePlex RP v2 Panel for detection and identification of respiratory viral and bacterial nucleic acids in nasopharyngeal swab (NPS) samples to support FDA regulatory premarket submissions/ notifications for Emergency Use Authorization. The proposed clinical testing includes testing of 1000 archived clinical specimens collected from collaborative sites across the United States (tested in triplicate) from patients of all ages and genders presenting with signs and/or symptoms of respiratory infection across three unique reagent lots and across three external sites. A total of approximately 3000 ePlex RP v2 consumables will be required to support the clinical evaluation study. The archived clinical specimens were verified to be positive for the relevant organisms by analytically validated PCR amplification assay(s). The study design will incorporate recommendations for establishing the clinical performance of highly multiplexed *in vitro* diagnostic devices described in the document "Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices" (FDA 2014), as well as recommendations made by FDA upon review of Emergency Use Authorization submission.

Success Metric for Completion of Deliverable 3:

Regulatory documentation to support distribution of the ePlex RP v2 Panel (e.g., FDA letter to authorize emergency use of the ePlex RP v2 Panel).

PROGRAM MANAGEMENT

The contractor shall provide the following as outlined below:

a) The overall management, integration, and coordination of all contract activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and direction of all contract activities;

b) A Principal Investigator (PI) or Project Manager (PM) responsible for project management, communication, tracking, monitoring, and reporting on status, progress, and modifications to the project requirements, deliverables and timelines, including projects undertaken by subcontractors;

c) A PM with responsibility for monitoring and tracking day-to-day progress and timelines of deliverables, coordinating communication and project activities, costs incurred, and program management.

d) A BARDA liaison (maybe be the PM) with responsibility for effective communication with the Contracting Officer (CO), Contract Specialist (CS), and Contracting Officer's Representative (COR);

e) Administrative and legal staff capable of developing compliant subcontracts, consulting, and other legal agreements, while also ensuring timely acquisition of all proprietary rights, including intellectual property (IP) rights and reporting all inventions made in the performance of the contract;

f) Administrative staff capable of financial management and reporting on all activities conducted by the contractor and any subcontractors;

g) Contract Review Meetings

The contractor shall participate in regular meetings to coordinate and oversee the contract effort conjointly with the CO, CS, and COR. Such meetings may include, but are not limited to, the following:

- Meeting with the contractors and subcontractors to discuss clinical manufacturing progress, product development, product assay development, scale-up manufacturing development, clinical sample assays development, preclinical/clinical study designs and regulatory issues.

- Meeting with individual contractors and other government officials to discuss the technical, regulatory, and ethical aspects of the program.

- Meeting with technical consultants to discuss technical data provided by the contractor.

h) The contractor shall participate in daily to twice monthly teleconferences with the CO, CS and COR to discuss the performance of the contract, unless otherwise directed. Teleconferences or additional face-to-face meetings may be more frequent at the request of the CO.

i) Gantt Chart

Within 15 business days of the effective date of the contract, the contractor shall submit a first draft of an updated Gantt Chart to the CO, CS and COR for review. The Gantt Chart shall be incorporated into the contract and will be used to monitor performance. The contractor shall include the key milestones, deliverables, and Go/No-Go decision gates.

j) Project Management Plan

In the management of this contract, the contractor is encouraged to utilize Project Management tools/techniques to track and monitor the cost and schedule of the project. The contractor and the government agree that at a minimum, the contractor shall utilize the cost and schedule tools/techniques in the contract deliverable for project management purposes.

k) Risk Management Plan

The contractor shall develop a high-level risk management plan within 30 days of contract award highlighting potential problems or issues that may arise during the life of the contract, including the impact on cost, schedule, and performance. Appropriate remediation plans. should reference relevant work segments where appropriate. Updates to this plan shall be included, at a minimum, on a monthly basis (or as needed) in the monthly Project Status Report.

l) Monthly and Annual Reports

The contractor shall deliver Project Status Reports on a monthly basis. The reports shall address the items below cross referenced to the SOW or other Project Management Plan tool(s):

- Executive summary highlighting the progress, issues, and relevant manufacturing, non-clinical, clinical, and regulatory activities.

- Progress in meeting contract deliverables, detailing the planned progress and actual progress during the reporting period, explaining any differences between the two and corrective steps.

- Updated Risk Management Plan (monthly, or as needed).

- One-month rolling forecast of planned activities.

- Progress of regulatory submissions.

m) Data Management

The contractor shall:

- Develop and implement data management and quality control systems/procedures, including transmission, storage, confidentiality, and retrieval of all contract data.

- Provide for the statistical design and analysis of data resulting from the research.

- Provide raw data or specific analyses of data generated with contract funding to the CO, CS, and COR, upon request.

REGULATORY

The contractor shall perform the following as outlined below:

a) Engage the Food and Drug Administration (FDA) on a path to support the use of the product for the Emergency Use Authorization.

b) Prepare materials for and requesting, scheduling, and participating in all meetings with the FDA, including meetings to review all data packages.

c) Provide BARDA with (1) initial draft minutes and final draft minutes of any formal meeting with the FDA, and (2) final draft minutes of any informal meeting with the FDA.

FACILITIES, EQUIPMENT, & OTHER RESOURCES

The contractor shall provide equipment, facilities, and other resources required for implementation of the SOW to comply with all Federal and HHS regulations in:

a) The humane care and use of vertebrate animals.

b) The acquisition, handling, storage, and shipment of potentially dangerous biological and chemical agents, including select agents under biosafety levels required for working with the biological agents under study.

Attachment 2

SAMPLE INVOICE REQUEST

(a) Designated Billing Office Name and Address: DHHS/OS/ASPR/BARDA ATTN: Contracting Officer O'Neill House Office Building Washington, DC 20515 (b) Contractor's Name: _____ Contractor's Address _____ _____ _____ Contractor's EIN: _____ Contractor's CAGE: _____ Contractor's DUNS: _____ Point of Contact Name, Title, Email, Phone: _____ _____ _____ _____	(c) Invoice No.: _____ (d) Date Invoice Submitted: _____ (e) Contract No.: _____ (f) Current Contract Period of Performance: _____ (g) Total Price of Contract: _____ (h) Total Fixed-Fee (if applicable): _____ (i) Invoicing Type: Three-Way Match (j) Office of Acquisitions: DHHS/OS/ASPR/BARDA ATTN: Contracting Officer O'Neill House Office Building Washington, DC 20515 (k) Central Point of Distribution: N/A

(l) This invoicing request represents reimbursable costs for the period from:

CLIN No.	Unit	(m) Current Amount	(n) Cumulative Amount	(o) Total Contract Amount
_____	_____	_____	_____	_____

Brief description of the work/deliverable(s) being invoiced:

I certify that all payments are for appropriate purposes and in accordance with the contract.

_____ _____

(Name of Official) (Title)

Note: Please attach supporting documents and details as specified in the contract to support the work/deliverable(s) being invoiced

Attachment 3

Schedule of Payments

Pursuant to FAR 52.232-2, partial payments will be made upon receipt and acceptance of a deliverable and acceptable invoice for partial delivery of work, as outlined in the table below:

Partial Payment	Deliverable Title	Brief Description of Deliverable	Partial Payment Amount
1	Project Plan	Detailed project plan outlining the goals, deliverables, and intended pathway for the project. This plan should also include a Gantt Chart, Risk Management Plan, and indicate the tools/techniques used to track and monitor the cost and schedule of the project.	$25,000
2	Feasibility and Development Completion	Completion of feasibility studies and development activities to add the SARS-CoV-2 assays to the ePlex Respiratory Pathogen panel cartridge design including the previously characterized and FDA-cleared pathogen targets and optimize the performance of this test in combination with more than 20 other assays.	$535,000
3	Verification/ Validation and Clinical Study Completion	Regulatory documentation to support distribution of the ePlex RP v2 Panel (e.g., FDA letter to authorize emergency use of the ePlex RP v2 Panel).	$189,000
4	(1) Final Report; and (2) Final Data Package	(1) Final report to include a summation of the work performed and results obtained for the entire contract period of performance. (2) Final data package consisting of all raw data produced under this contract. Data may be used by DRIVe for analysis, evaluation, shared with other agencies, or shared outside of the government consistent with FAR 52.227-14. This submission package must be delivered in a non-proprietary format.	There is no partial payment associated with the Final Report and Final Data Package.*

*The partial payment preceding the (1) Final Report and (2) Final Data Package (outlined in Section F of the contract) will not be paid until both the (1) Final Report and (2) Final Data Package are received and accepted by the Contracting Officer and Contracting Officer's Representative.